Planning and running an epidemiological study: Nepal Family Cohort

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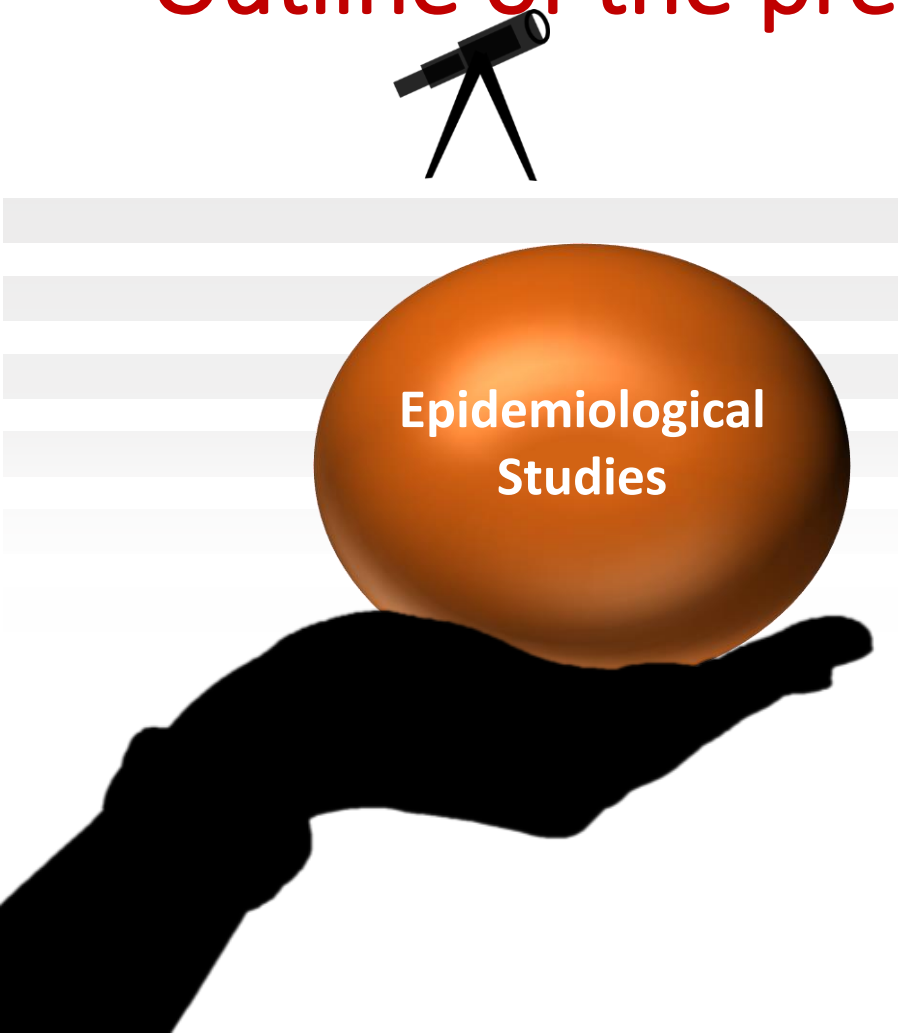
HEI Early-career training on Air Pollution and Health
12-14 August 2024, ICIMOD, Kathmandu, Nepal


MY HOUSE
Coventry University
McMaster University
University of Oxford
University of Birmingham
Post-graduate
Lumbini, Nepal (>125 years)

My journey

Outline of the presentation



- Epidemiological studies
- Planning the study
- Conducting the study
- Nepal Family Cohort Study

Why do you carry out an Epidemiological Study?

Pros/Cons of conducting an epidemiological study in South Asia.

Epidemiological Studies

Scope

Distribution and determinants of health-related conditions or events in specified populations, and the application of this study to the control of health problems.

Importance

It provides critical insights and evidence into the causes, prevention, and control of diseases, injuries, and other health-related conditions, thereby informing public health policies and suitable interventions.

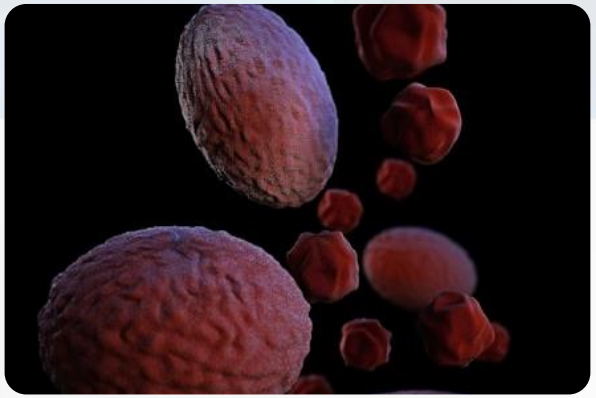
Tools

Epidemiologists employ various research methods, such as research designs, identify risk factors, and evaluate the effectiveness of interventions to control health problems

Public Health Policy and Practice

Evidence-Based Decision Making

Epidemiological evidence informs the development and implementation of public health policies.



Disease Surveillance

Studies contribute to disease surveillance systems, enabling early detection and response to outbreaks.

Health Promotion and Education

Findings support health promotion efforts and educational campaigns aimed at disease prevention

Global Health Equity

Addressing Health Disparities

Epidemiological research highlights disparities in health outcomes and supports efforts to achieve health equity.

Collaboration (National/International)

Studies foster collaboration between countries and organizations to address global health challenges.

Sustainable Development Goals

Epidemiological data contribute to monitoring progress towards achieving the UN Sustainable Development Goals related to health.

Epidemiology in LMICs

Importance of Research

- Epidemiological studies in LMICs are critical for understanding the burden of diseases,
- identifying risk factors
- Identify high-risk groups
- developing targeted interventions
- Informing resource allocation

Global Health Impact

- Findings from these studies contribute to global health knowledge and
- inform strategies for addressing health disparities.

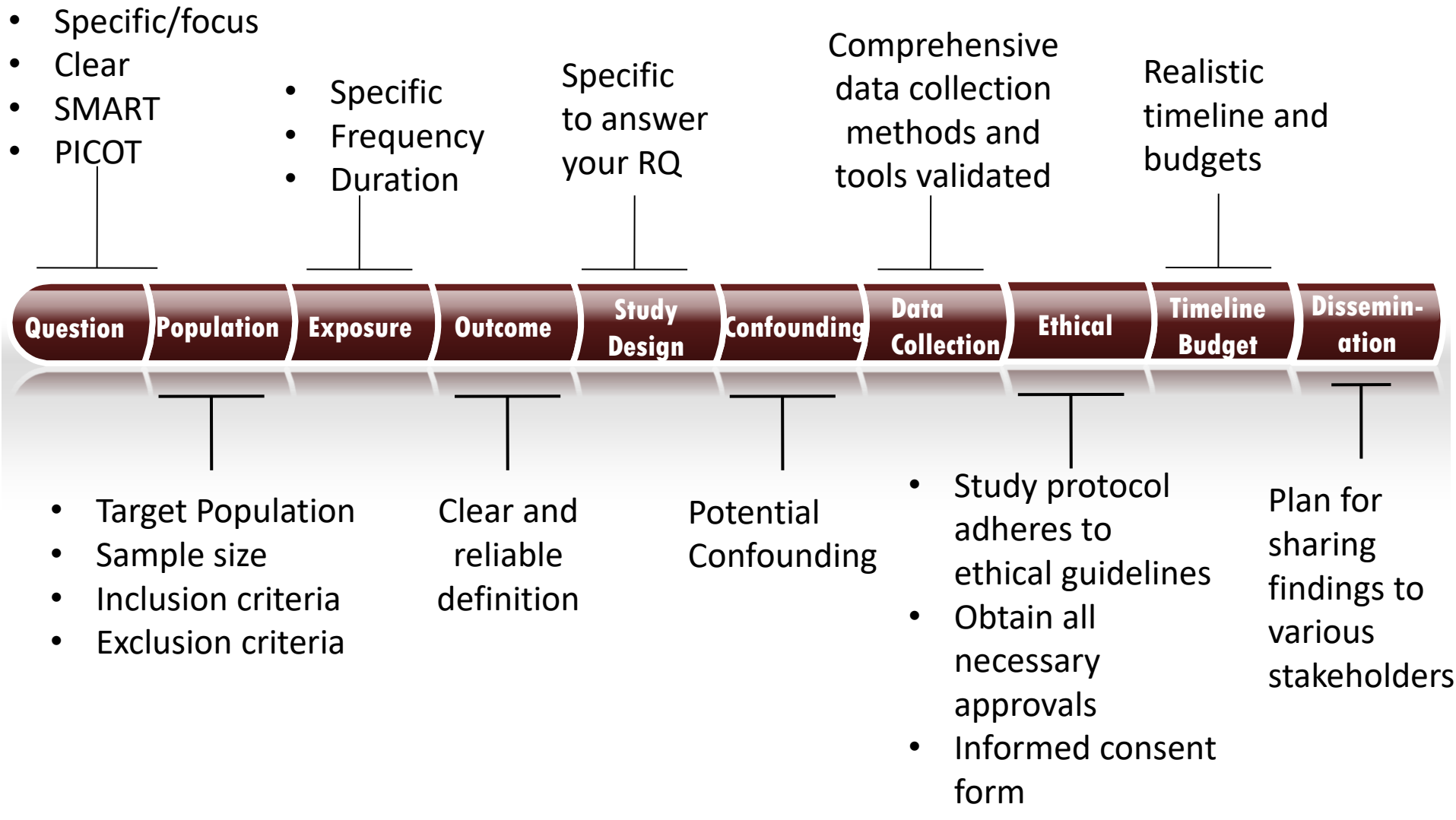
Unique Challenges/Opportunities

LMICs face specific challenges/opportunites related to

- limited resources,
- diverse cultural contexts, and
- varying healthcare infrastructure.

Planning an Epidemiological Study

Study Design consideration



Defining Research Objectives

Formulating Research Questions

Clear research questions guide the study design and data collection process.

Setting Objectives and Hypotheses

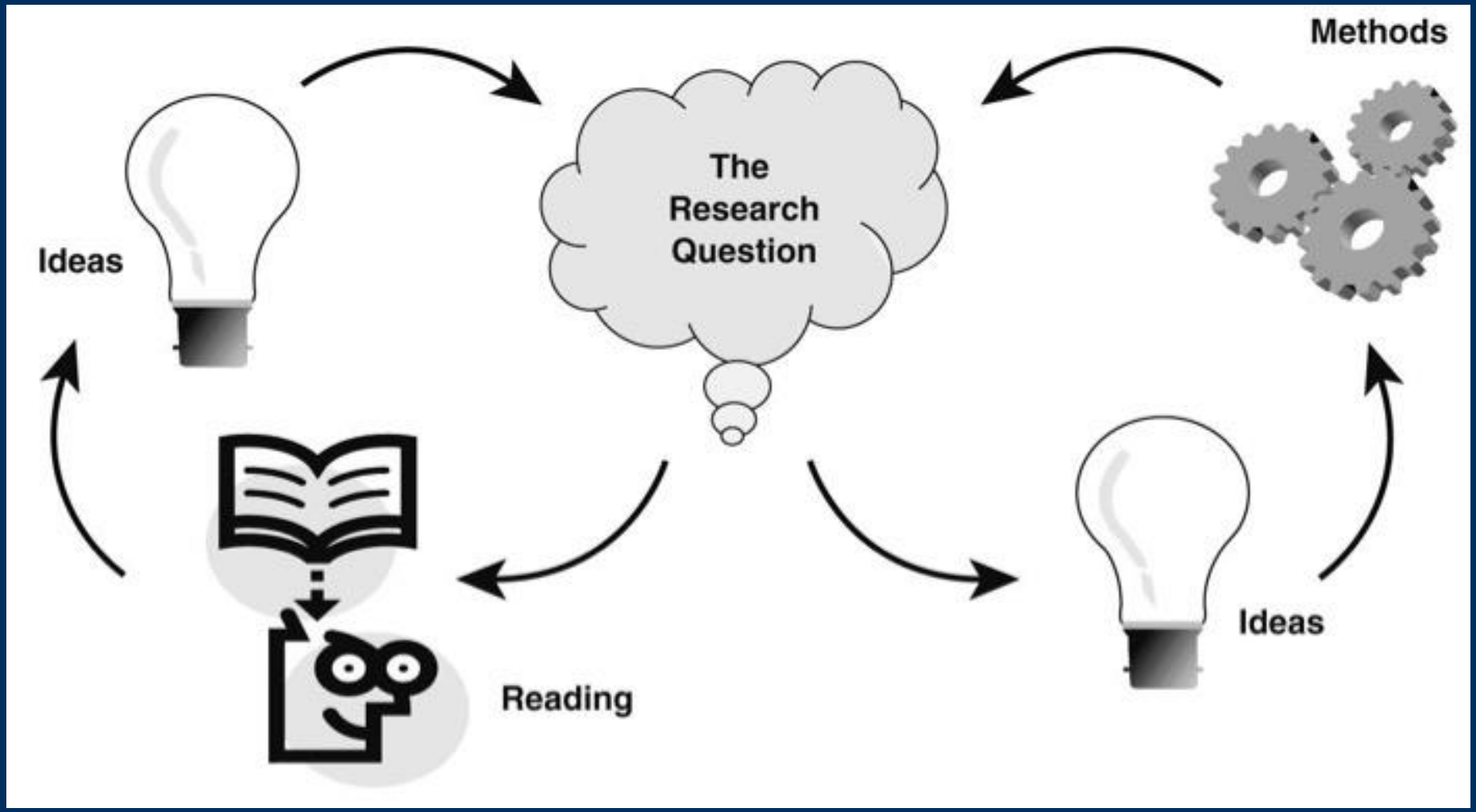
Establishing specific objectives and hypotheses ensures focused and meaningful research outcomes.

Ethical Considerations

Addressing ethical issues related to study participants and data management is integral to the planning phase.

How do you come up with a Research Question?

Cycles of Research Question Development



Framing the Research Question

P — In older patients with existing cardiovascular disease…

I — is higher exposure to $PM_{2.5}$ associated with…

C — *[not needed for 'continuous' (ie, non-categorical) exposures since "I" covers comparison group, ie, "associated with"]*

O — greater recurrence of myocardial infarction, stroke, heart failure, and total mortality…

T — after five years of follow-up?

Choosing the Right Study Design (from WHO)

	Ecological	Cross-Sectional	Case-Control	Cohort
Rare disease	++++	-	+++++	-
Rare cause	++	-	-	+++++
Test multiple effects of cause	+	++	-	+++++
Study of multiple exposures	++	++	++++	+++
Temporal relationship between exposure & outcome	++	-	+(a)	+++++
Direct measurement of incidence	-	-	+(b)	+++++
Investigation of long induction periods	-	-	+++	-

+....+++++ indicates the degree of suitability; - not suitable;
(a) If prospective; (b) If population based

Resource Mobilization and Collaboration

Budgeting & Funding

Planning for the financial resources required for personnel, equipment, and data analysis.

Stakeholder Engagement

Building partnerships with local organizations, healthcare providers, and community representatives.

Logistical Planning

Organizing logistics for fieldwork, participant recruitment, and data collection in diverse settings.

Data collection and management

Ethical Approval Consent

- Addressing ethical considerations, obtaining informed consent, and
- Ensure the safety, privacy, and dignity of study participants throughout the research process.

Quality Assurance Measures

- Ensuring data accuracy, reliability, and validity
- Rigorous quality control procedures
- Regular field supervision and monitoring
- Instrument calibration
- Data Storages/access

Developing Data Collection Tools

- Designing surveys, questionnaires, and other instruments for systematic data collection
- Tailoring data collection methods to the cultural, linguistic, and environmental contexts of the study population.
- Equipping field staff with the necessary skills for data collection, ethical conduct, and participant interactions
- Biological samples

Conducting the Study

Participant Recruitment and Enrollment

Informed Consent Process

Ensuring participants understand the study objectives, procedures, and risks before consenting to participate.

Recruitment Strategies

Implementing effective recruitment approaches to reach diverse participant groups and ensure representation.

Community Engagement

Involving local communities in the study process and addressing cultural sensitivities.

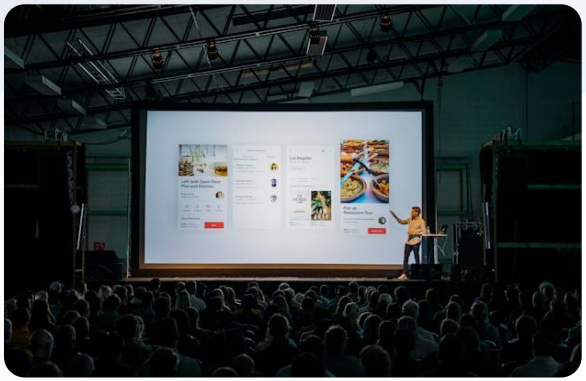
Data Analysis and Interpretation

Quantitative and Qualitative Analysis

Appropriate statistical and analytical methods to interpret the collected data.

Interpreting Findings

Drawing meaningful conclusions and implications from the data to address the research objectives.



Dissemination of Results

Planning for the communication of findings to stakeholders, policymakers, and the scientific community.

Addressing Limitations and Biases

Methodological Limitations

Acknowledging and addressing potential biases, confounders, and limitations in the study design.

Data Quality Assurance

Strategies for ensuring data accuracy, completeness, and reliability during analysis and interpretation.

Sensitivity Analyses

Conducting sensitivity analyses to assess the robustness of findings and explore alternative scenarios.

Translating Research into Action

Community Engagement Activities

Involving communities in the interpretation of results and the development of targeted interventions

Advocacy and Awareness

Communicating research outcomes to raise awareness and advocate for health policy changes

Public Health Intervention

Identifying opportunities for implementing evidence-based interventions based on the study findings

Nepal Family Cohort Study (NeFCoS)

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डा. तारा बिन्देल, पीएचडी
युनिभर्सिटी अफ क्यालिफोर्निया सान फ्रान्सिस्को, यु.एस.ए.
डा. इमरान सातिया, एम.डी.
म्याकमास्टर विश्वविद्यालय, ह्यामिल्टन, क्यानडा
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डा. पुष्पराज पन्त, पीएचडी
निरी, नेपाल

Our Partners

NIRI | BU Bournemouth University | Coventry University | McMaster University | The University of Nottingham | KIOCH | University of Huddersfield Inspiring global professionals

Knowledge gap

Long term health effects extrapolated from the West, failing to account for:

- Varying pollutant levels
- Differing pollutant compositions
- Climatic differences
- Population and healthcare characteristics
- Imprecise measurement of other determinants

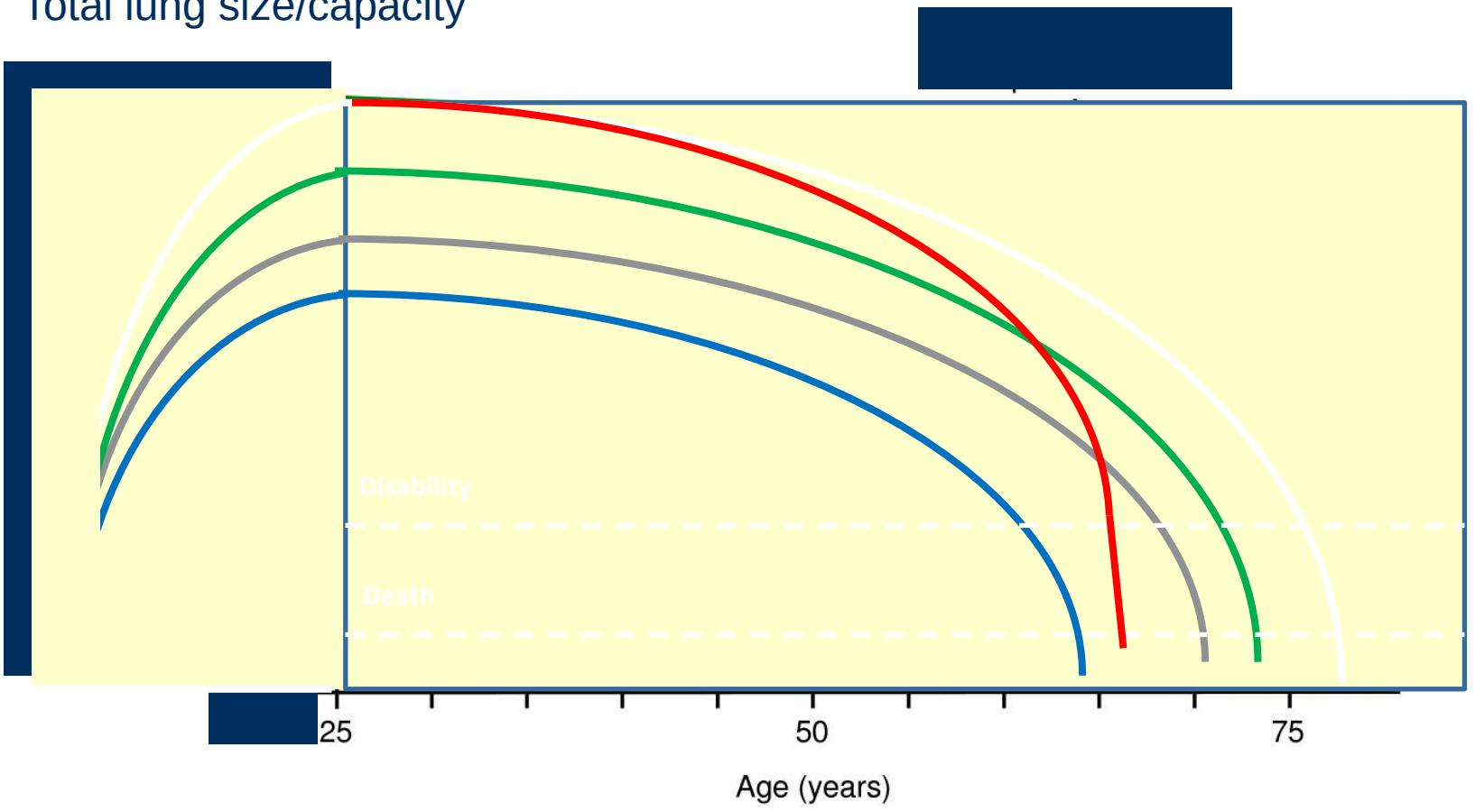
Needs contemporary data from Nepal

- Large population-based prospective study with reliable outcome ascertainment
- Geographical variations: urban/rural, north/south
- More detailed individual exposure profiling
- Requirement of biomarkers

Primary aim

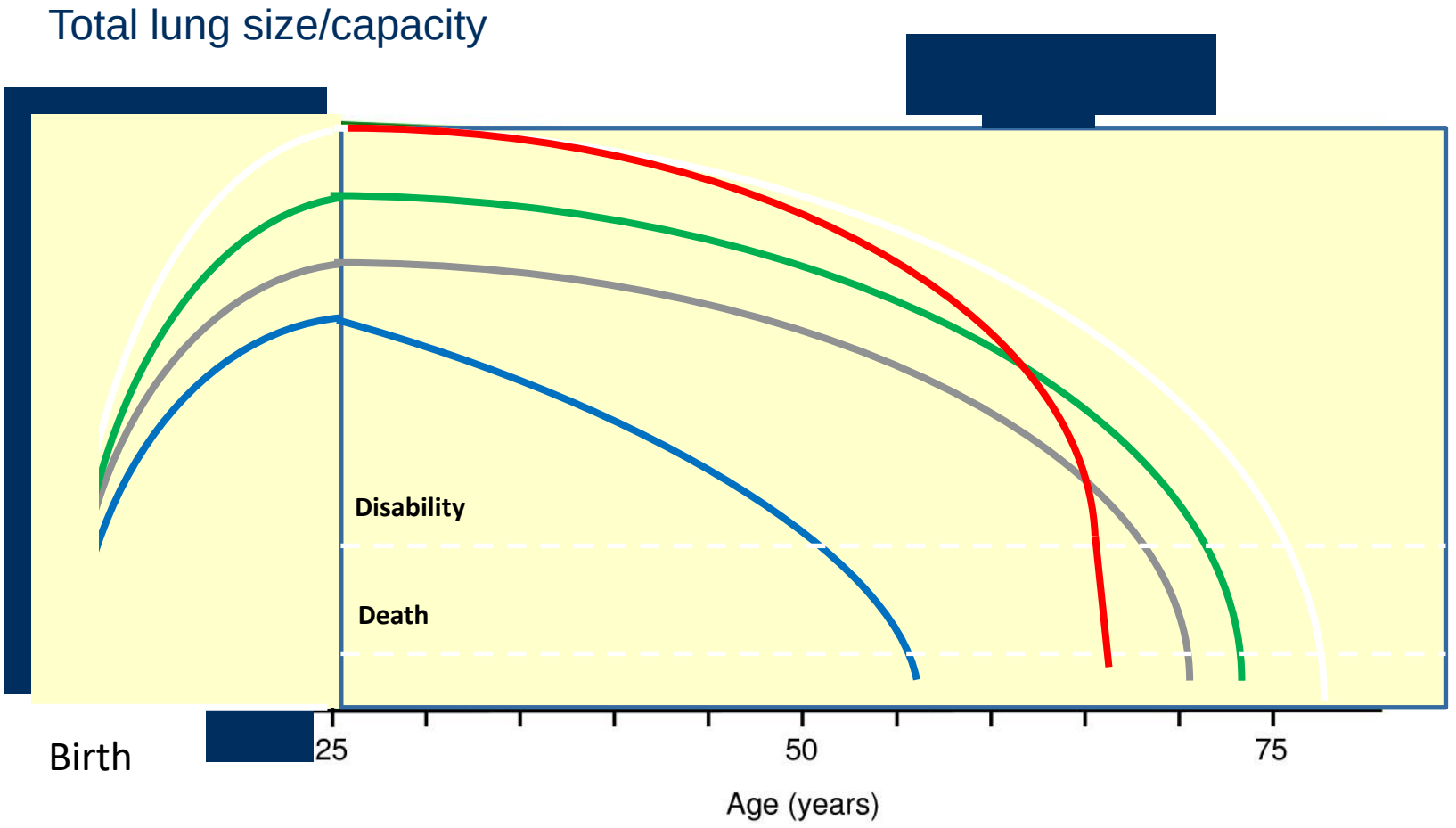
The primary aim of this Nepal Family Cohort study is to establish a longitudinal cohort of children and their parents in Nepal to understand the prevalence, incidence and determinants of lung and other health conditions from childhood to adulthood using a life course epidemiology approach.

Putting it together: life course of non-communicable lung disease



Early life interventions: a lifetime of healthy lungs
Easier said than done

Putting it together: life course of non-communicable lung disease



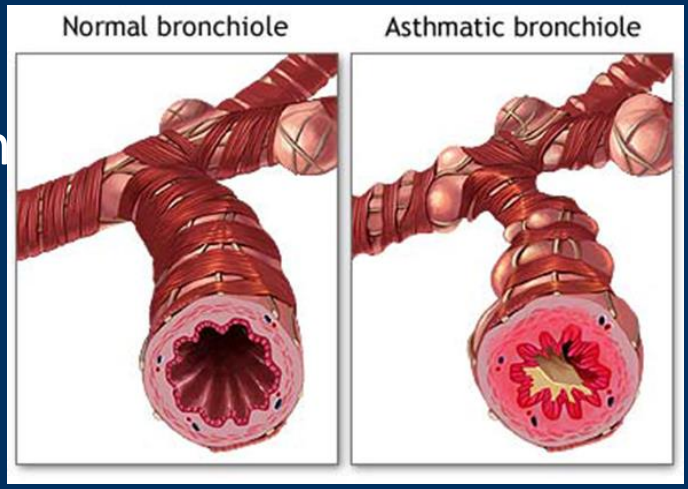
FEV1 decline:	HIC healthy:	20-30ml/yr
	HIC COPD:	40-50ml/yr
	Malawi ‘healthy’	46-53ml/yr

Asthma

- 262 million affected, 410,000 deaths
- Disease of westernisation, urbanisation
- In many LMICs ↑ than global average,
  - prevalence↑80% of deaths are in LMICs
- In LMICs, underdiagnosed, undertreated, high morbidity and mortality

Nepal

- Prevalence of asthma symptoms in children 5-9%
- 1% children with asthma diagnosis
- 5900 asthma deaths a year, (9th leading cause of death)
- Age adjusted mortality rate of 30.9/100,000 (6th highest in the world)



COPD

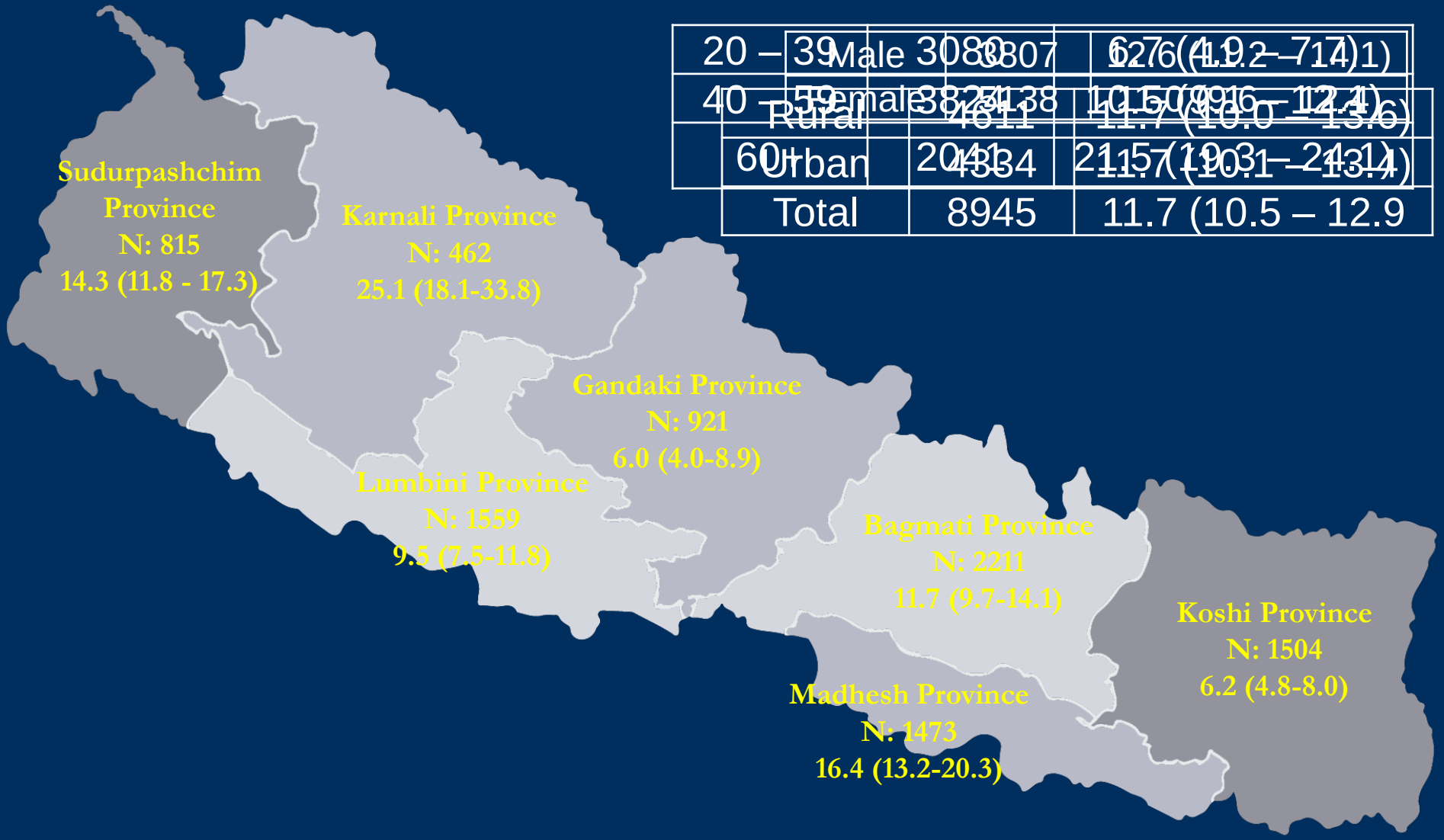
Nepal

Prevalence	8.5-12% adults	(UK 2% diagnosed, 6% total)
The leading cause of death	94.5/100,000	(UK #6 48.7/100,000)
Third leading cause of DALYs	2082/100,000	(UK #3 1173/100,000)

Globally- in top 4 for DALYs

17.1% of adults (28.0% of men, 7.5% of women) current smokers

(UK 14.1% of adults, 15.9% of men, 12.5% of women)



20 – 39	3807	627 (4.1 – 7.1)
40 – 59	3834	1015 (9.6 – 12.1)
60+	1304	2157 (19.1 – 24.1)
Total	8945	11.7 (10.5 – 12.9

Male	3080	627 (4.2 – 7.1)
Female	5865	1530 (11.6 – 14.4)
Rural	4611	1150 (8.6 – 11.4)
Urban	4334	2157 (19.1 – 24.1)
Total	8945	11.7 (10.5 – 12.9

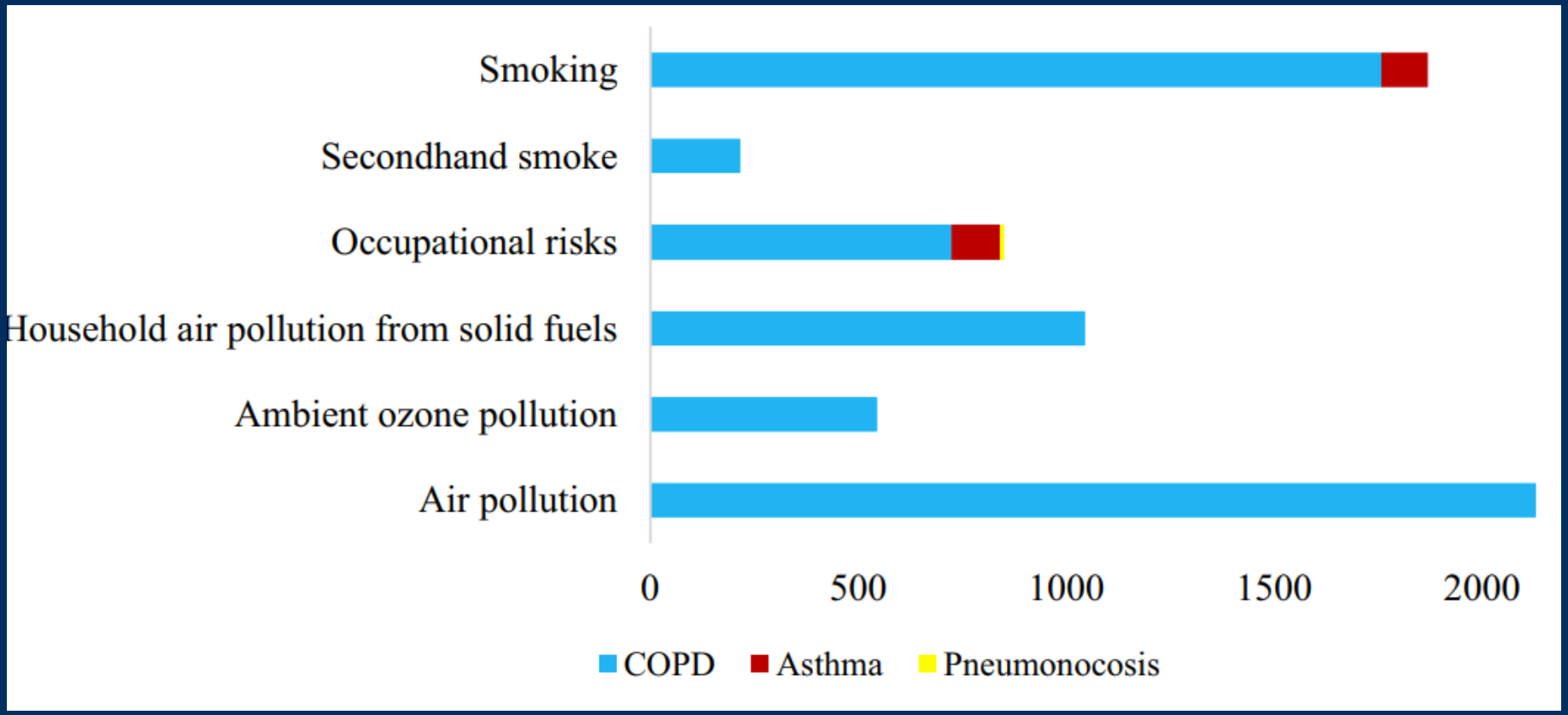
Source: Nepal Health Research Council (NHRC), 2019

Factors influencing lung HEALTH/growth

- **Factors influencing during fetal and neonatal development, infancy, childhood and adolescence**
  - ***Intrauterine growth retardation/premature birth***
    - ↓ BW & postnatal growth- ↓LF in adulthood

      (**Hanco**x et al. Thorax 2009;64:228-32)
  - ***Lifestyle factors:***
    - *Diet/nutrition*
    - *Physical activities*
  - **Environmental toxicants**
    - Smoking
    - Exposure to air pollutants
  - **Genes** (production of redox particle) (**Vawda** *et al*. AJE 2013;179: 432-42)
    - GSTM1 null & GSTP1 val 105 allele-↓annual growth in FEV1
    - TNF- α 308G>A , TLR4 & TGFβ1 polymorphism-509C>T

Major Risk factors in Nepal



Adhikari et al., Health Sci. Rep. 2023;6:e1091

Exposure to HAP and lung growth

Eur Respir J 2013; 41: 25–30
DOI: 10.1183/09031936.00220511

Reduced lung function due to biomass smoke exposure in young adults in rural Nepal

Om P. Kurmi*, Graham S. Devereux#, W. Cairns S. Smith¶, Sean Semple#, Markus F.C. Steiner#, Padam Simkhada¶, Kin-Bong Hubert Lam* and Jon G. Ayres*

ABSTRACT: This study aimed to assess the effects of biomass smoke exposure on lung function in a Nepalese population, addressing some of the methodological issues seen in previous studies.

We carried out a cross-sectional study of adults in a population exposed to biomass smoke and a non-exposed population in Nepal. Questionnaire and lung function data were acquired along with direct measures of indoor and outdoor air quality.

Ventilatory function (forced expiratory volume in 1 s (FEV_1), forced vital capacity (FVC) and forced expiratory flow at 25–75% of FVC) was significantly reduced in the population using biomass across all age groups compared to the non-biomass-using population, even in the youngest (16–25 yrs) age group (mean FEV_1 (95% CI) 2.65 (2.57–2.73) *versus* 2.83 (2.74–2.91) L; $p=0.004$). Airflow obstruction was twice as common among biomass users compared with liquefied petroleum gas users (8.1% *versus* 3.6%; $p<0.001$), with similar patterns for males (7.4% *versus* 3.3%; $p=0.022$) and females (10.8% *versus* 3.8%; $p<0.001$), based on the lower limit of normal. Smoking was a major risk factor for airflow obstruction, but biomass exposure added to the risk.

Exposure to biomass smoke is associated with deficits in lung function, an effect that can be detected as early as the late teenage years. Biomass smoke and cigarette smoke have additive adverse effects on airflow obstruction in this setting.

KEYWORDS: Airflow obstruction, biomass, indoor air pollution, lung function

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Received:
Dec 14 2011

Nepal

- n-3 PUFA intake in Nepal is extremely low (<50mg/d)

- Global survey of blood n-3 PUFA unable to comment on Nepal, but India and China had very low/low blood DHA/EPA concentrations

- Bhaktapur, Nepal, lactating women and their infants in Bhaktapur
  - low dietary fat and fish intakes, low blood DHA/EPA concentrations.

- Sarlahi, Nepal, first trimester women
  - 14% severely vitamin D deficient (<25nmol/l)
  - 50% vitamin D deficient (<50nmol/l)
  - 50% vitamin E deficient
- Bhaktapur, Nepal:
  - 81% of pregnant women vitamin D deficient (<50nmol/l).

EXPOSURE TO HAP AND SGA IN NEPAL

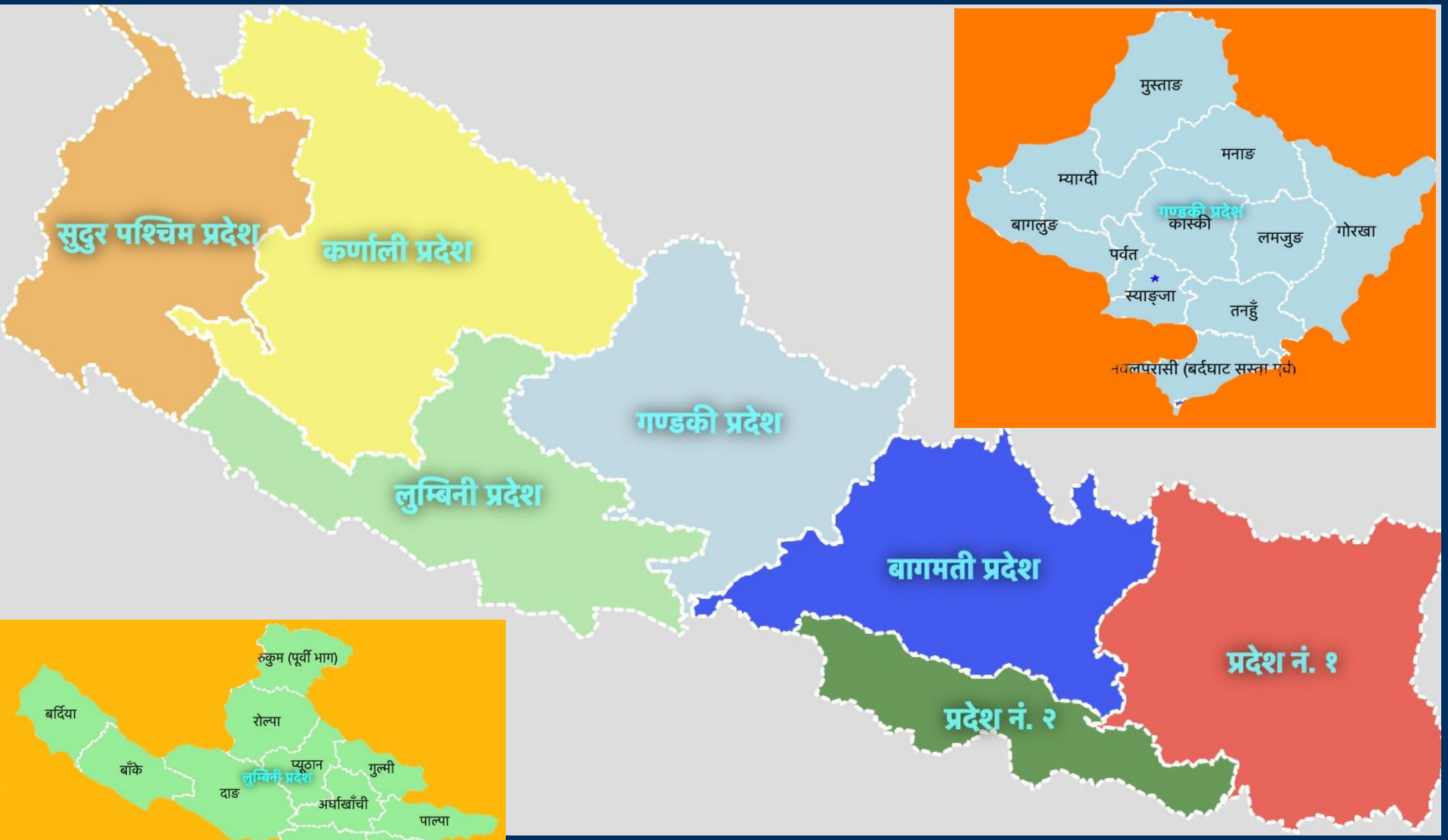
- Prognostic factors of SGA (2017)
- 4000 babies born in a tertiary hospital in Western Nepal

	Total	HAP
Normal weight for gestational age (AGA):	3078 (77%)	701 (22.8%)
Small for gestational age (SGA)	: 813 (20.3%)	518 (63.7%)
Large for gestational age (LGA)	: 109 (2.7%)	7 (6.4%)

- >5-fold ↑ risk: 5.4 (4.1-6.9)

Chaudhary *et al*. Health Sci Rep. 2021;4:e250

Establishing a Family Cohort in Nepal



METHODS and Study Centres

- **Design**: Prospective cohort with intervention component built-in first 3-year of project, Plan to follow-up until adults
- **Sampling population**
  - Children of 6-14 years old and their parents
- **Collaborators**
  - Nepal (Local)
    - Nexus Institute of Research and Innovation (NIRI)
    - Universal College of Medical Sciences (Plain region)
    - Kathmandu Institute of Child Health (Hilly region)
  - UK collaborators/partners
    - Imperial College, University College London, Bournemouth University, Nottingham University, Huddersfield University
  - Other collaborators
    - McMaster University, Hamilton, Canada
    - ISGLOBAL, Spain
    - University of California San Francisco

Primary exposures/outcomes

Exposures

Maternal exposure to household & ambient air pollution, occupational exposures

Lifestyle factors

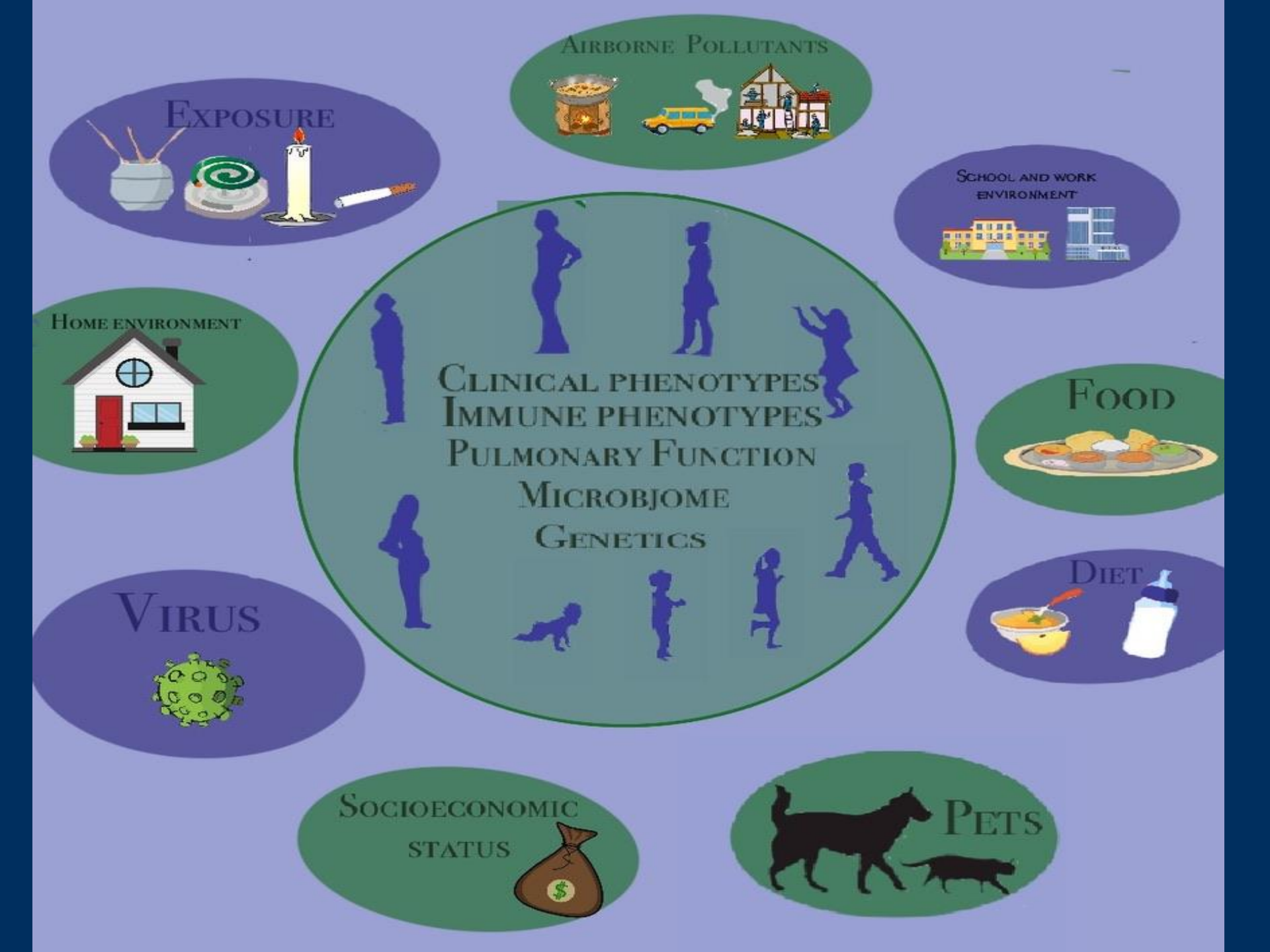
Diet, smoking, alcohol intake, physical activity

Primary health outcomes

Respiratory (lung function, asthma, ALRTI)

Populations

Parents, children (5-14 years old)

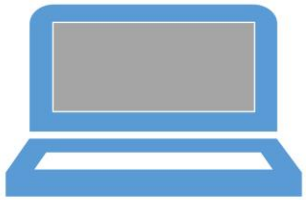

Airborne Pollutants
Exposure
School and work environment
Home environment
Clinical phenotypes
Immune phenotypes
Pulmonary Function
Microbjome
Genetics
Food
Diet
Virus
Socioeconomic status
Pets

QUESTIONNAIRES

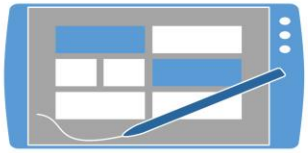
i. Background information
ii. Tea/coffee drinking
iii. Alcohol consumption
iv. Smoking history
v. Diet (24-hours recall FFQs)
vi. ETS and air pollution
vii. Personal and family medical history
viii. Physical activities and occupational history
ix. Reproductive history
x. Sleeping, mood and mental situation
xi. Physical examination
xii. Additional questionnaires
    a. COPD
    b. Depression/Anxiety
    c. Frailty

Measurements

i. Anthropometry
ii. Height, weight
iii. Bio-impedance
iv. Blood pressure
v. Spirometry (post-bronchodilator)
vi. Exhaled CO
vii. Oxygen saturation
viii. Hand grip strength
ix. Temperature and RH
x. On spot tests
    i. Blood sugar (FU)
    ii. Lipids (FU)
    iii. Urine
xi. Biological samples storage (-
    i. Urine (Testing of black carbon) (FU)
xii. Personal air pollution (CO measurement)
xiii. $PM_{2.5}$ area measurement
    i. Centroid of village (AAP)
    ii. CO and $PM_{2.5}$ sampler co-located (subset)

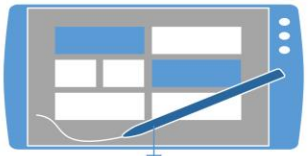


Registration, Consent & Assent form



Parent, FFQ, and child questionnaire

Circumference + Height + Skinfold thickness
Anthropometry station



Children Clinical assessment form to be completed by healthcare professional

Air Pollution measured at the centroid of each village and selected participants homes

Pulmonary function + FeNo
Lung health assessment station

Bioimpedance + Blood pressure + exhaled CO + Pulse Oximeter
Physiological measurement station

Flow diagram of data collection process in the study

Baseline Recruitment

Total Participants

- Total families: 5,829
- Total participants: 16,826
- Total parents: 7,601
- Total children: 9,225
  - Boys: 4,863
  - Girls: 4,362

With Spirometry

- Total families: 5,829
- Total participants: 16,043 (95.3%)
- Total parents: 7,267 (95.6%)
- Total children: 8,776 (95.1%)
  - Boys: 4,636 (95.3%)
  - Girls: 4,140 (94.9)

My suggestion for early career researchers

- Selection of place and mentor
- Holistic assessment of exposure
- Outcome, well defined for comparison
- Time management
- Involvement of community workers from the very beginning and at all stages of the project.
- Don’t be afraid to seek help

Funding support:

1. McMaster University, Canada
2. ANMF, USA
3. Bournemouth University and University of Huddersfield, UK
4. Nepal Health Research Council
   (Provincial grant)

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Thank you